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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,542	05/16/2001	Rajesh Manchanda	BERLX-100	9728

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EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,542

Applicant(s)

MANCHANDA, RAJESH

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/13/05, 2/8/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-22 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 7, 11-14, 16-22 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 08, 2005 and June 18, 2005 have been entered.

***Election/Restrictions***

2. Applicant's election with traverse of Group I, claims 1-4, 6-10, 32-33 and the species directed to Tc-99m, depreotide and iodide ion, in the reply filed on June 13, 2005 is acknowledged. The traversal is on the ground(s) that full examination has been conducted in this application without any previous restriction. Applicant argues that since the claims have been fully searched no serious burden is imposed on the Examiner. This is not found persuasive because as the full scope of the presented claims were never examined throughout the prosecution and Applicants' claim amendments have modified the scope of the originally presented claims.

In response to applicant's arguments about the extent and scope of examination, Examiner states that this application has been subject to earlier restrictions on Aug 20, 2002, and Nov 18, 2002. Applicant had then elected merely inventions and species directed to compositions comprising Tc99, depreotide and potassium iodide. At no point during the examination of this application, had examiner made any statement that the search was extended beyond the scope of the elected species. Nor is there any

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evidence on record that the examination was extended to the entire scope of the claims and beyond the originally elected species.

In fact, on the Office Action filed on March 12, 2003, Examiner withdrew her earlier position of declaring an allowable subject matter and continued the search and subsequent examination on the originally elected species directed to Tc-99m, depreotide and iodide ion. Therefore applicant's arguments that full examination and prosecution of restricted groups have already occurred in this application is simply without merits and is incorrect.

Moreover, the Restriction Requirement is discretionary to expedite the prosecution. Since the scopes of the claims have been modified throughout the prosecution, Examiner has requested for a Restriction Requirement based on the guidelines articulated in MPEP § 806. Accordingly, as classification is prima facie evidence of undue burden of search, the examiner has established reasons for the Restriction Requirement. Thus, for the reasons set on the filing of the requirement filed on May 23, 2005, the requirement is still deemed proper and is therefore made FINAL.

Claims 7, 11-14, 16-22, 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 13, 2005.

Claims 1-4, 6, 8-10, 32-33 are under consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6, 8-10, 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of phrase containing the language "optionally as a part of a compound or complex,..." and its subsequent limitations, in claims 1 and 32 renders the claim scope of the claim vague and ambiguous. Specifically, it is not clear what are the optional components of the instant composition claims? Is it the targeting agent only, or are the targeting agent and the iodide ions, both viewed to be optional? The language of the claim is not specific as to the mandatory limitations of the instant claims. Thus, the scope of the claim is ambiguous.

The recitation of "a compound or complex" in line 2 of claim 1 and line 1 of claim 32 lack antecedent basis. It is not clear to what compound or complex is applicant referring?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 10, 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Solanki US Patent 5,262,175.

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The instant claims are directed to compositions comprising a radionuclide such as Tc-99m, optionally a targeting agent preferably a peptide, and iodide ions. For purposes of applying art, even though the language of claims are not clear, Examiner has interpreted "targeting agent" component of the instant compositions to be an optional ingredient. Accordingly, the "targeting agent" or "peptide" component is not viewed to positively limit the claims because its existence in the claimed composition is optional. Therefore, the broadest reasonable interpretation of the instant claims is directed to a composition comprising a radionuclide excluding iodine radionuclide and iodide ions.

Solanki meets the limitations of the instant claims. Solanki teaches the use of weak oxidizing agents such as iodine, iodophores and povidone iodine to stabilize the radiopharmaceutical complex compositions. (col 2, lines 1-8). Solanki teaches preparing a Tc-99 containing composition by mixing lyophilized Tc-99m hexamethylpropyleneaminoxime (HMPAO) complex with 0.4 mg of sodium iodide. (see col 7, line 55-67). Solanki then claims methods of stabilizing a radiopharmaceutical complex with weak oxidizing agents such as iodine, iodophores and povidone-iodine. (see col 8, line 50-col 9, line 5). The iodine component of Solanki is viewed to meet the instant limitation "iodide ion or iodide ion generating compound." Thus, Solanki anticipates the limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6, 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solanki in view of Cyr et al US Patent US 6,881,392.

The teachings of Solanki are described above. Solanki teaches the addition of weak oxidizing agents such as iodine salts to radiopharmaceutical complexes including Tc-labeled compositions. Solanki only fails to specifically recite the use of depreotide in his formulations.

Cyr is used to establish the state of art in using targeting peptides as stabilizers to increase the shelf life of radiopharmaceuticals (see col 5-15). Cry specifically teaches the use of Tc-labelled somatostatin receptor-binding peptide deproetide (col 15, line 1-col 18; col 44, lines 36-59). Cyr also encourages the addition of any suitable pharmaceutical agent for preparing his formulations (col 15, lines 8-40). Applicant is also put in notice that Cyr's effective filing date antedates the effective filing date of the instant application, because Cyr's CIP parent application adequately described the instantly relied teachings. (see attached priority documents at pages 22-27 of US App 09/695,360, now abandoned). Thus, Cyr is a competent prior art.

It has been held *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to combine a weak oxidizing agent such as iodine salts of Solanki with the Tc-labelled formulations of Cyr, because both formulations are directed for the same purpose and combining them would flow logically from their having been individually taught in prior art. Further, as stated by Solanki, the ordinary skill in the art would have had a reasonable expectation of success in achieving a stable radiopharmaceutical formulation when adding iodine salt described by Solanki , to a Tc-labelled containing radiopharmaceutical compositions.

### **Conclusion**



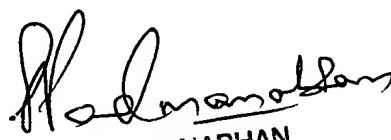
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No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER